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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,976	11/25/2003	Leon Kaufman	021106-001610US	6927
20350	7590	07/19/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			CHENG, JACQUELINE	
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,976	KAUFMAN, LEON	
	Examiner	Art Unit	
	Jacqueline Cheng	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/7/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claim 13 is objected to because of the following informalities: Claim 13 claims dependency on itself. Examiner has examined claim 13 as dependent upon claim 2. Appropriate correction is required

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 7, 8, 13, 15-19, 21, 22, 27, 29, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,272,366 B1 (herein referred to as Vining).

4. **Claims 1-4, 7, 8, 15-18, 21, 22, 29:** Vining discloses virtual colonoscopy in which the patient goes through a preparation procedure wherein the patient's colon is initially cleansed and then inflated with air. To cleanse the colon the patient orally takes a clear liquid diet in conjunction with laxatives. Laxatives are bulking agents that due to their capacity to absorb water and soften stools, increases the speed of intestinal transit time. Cellulose (such as sawdust (Fuel from Sawdust, second paragraph, http://journeytoforever.org/biofuel_library/ethanol_sawdust.html)) and fat are well known in the art to be used as laxatives (see US Patent No. 4,568,557, col. 5 line 1-11, col. 3 line 11-14). By taking a liquid diet and laxatives the density of

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the patient's stool is lowered, water content increased, and the fat content increased, reducing the attenuation signal of the stool below the attenuation level of the surrounding colon tissue.

5. **Claim 5, 19:** The density of the patient's stool is decreased so that there is a difference between the stool and the colon tissue. At eighty to ninety percent density of the colon tissue is a difference in which the stool can be differentiated from the colon tissue.

6. **Claim 13, 27:** By taking laxatives that increases the fat content of the stool, the attenuation signal of the stool is lowered to between -100 HU to -200 HU as it is well known in the art that fat has an HU about -200 to -20 (US Patent No. 5,920,319 col. 9 line 5-6).

7. **Claim 35:** Vining discloses applying an attenuation threshold to isolate an organ of interest. Although Vining does not explicitly disclose applying a lower threshold than that of the patient's colon, the value of the threshold would depend upon the image and what the best way to isolate the colon.

8. **Claims 9 and 10, 23, 24** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vining as applied to claim 2 above, and further in view of US Publication No. 2004/0191213 A1 (herein referred to as Pelham et al.). Pelham et al. discloses that laxatives sometimes produce gas (paragraph 0038). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Pelham et al. with Vining as Vining uses laxatives, which can be the laxatives as described in Pelham et al.

9. **Claims 6 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Vining as applied to claim 4 above, and further in view of US Patent No. 6,042,809 (herein referred to as

Tournier et al.). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Tournier et al. with Vining as both inventors disclose using gas as a contrast agent for imaging.

Claim 11, 12, 25, 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vining in view of Pelham et al. as applied to claim 10 above, and further in view of Tournier et al. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Tournier et al. with Vining in view of Pelham et al. as Vining and Tournier et al. disclose using gas as a contrast agent for imaging.

10. Tournier et al. discloses that any suitable hollow bead-like particle filled with a contrast gaseous mixture provides good imaging agents. A polystyrene hollow bead filled with gas is a suitable hollow bead-like particle that will stimulate gas formation

11. Claims 13, 14, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vining as applied to claim 2 above, and further in view of US Publication No. 2005/0175542 A1 (herein referred to as Lefere et al.). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Lefere et al. with Vining as both inventions disclose methods for virtual colonoscopy.

12. **Claim 13, 27:** Vining discloses using a clear liquid diet, but does not disclose the specifics of the value of the signal size to lower the stool to. Lefere et al. discloses that the greater fluid presence in an area of stool, the lower the HU is (paragraph 0048).

13. **Claim 14, 28:** Lefere et al. discloses that the tagging agent impregnates the stool non-homogeneously (paragraph 0043).

14. Claims 30, 31, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lefere et al.

15. **Claim 30, 31:** Lefere et al. discloses a colonic residue tagging system, formulation, kit and method for use in preparing an individual for colon screenings such as virtual colonoscopy. In the kit contains fluids and nutrition to enable the individual to minimize the amount of stool formation. The minimizing of the stool formation is reducing the density of the patient's stool, lowering the attenuation signal.

16. **Claim 33:** Lefere et al. discloses that the tagging agent impregnates the stool non-homogeneously (paragraph 0043).

17. **Claim 32** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lefere et al. as applied to claim 30 above and further in view of US Patent No. 4,568,557 (herein referred to as Becker et al.). Becker et al. discloses using fat as part of the laxatives which would increase the fat content of the stool (col. 3 line 11-14). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Becker et al. with Lefere et al. as Lefere et al. discloses using a laxative to help clear the colon (paragraph 0007).

18. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lefere et al. as applied to claim 30 above and further in view of Pelham et al. Pelham et al. discloses that laxatives sometimes produce gas (paragraph 0038). It would be obvious to one with ordinary

skill in the art at the time of the invention to combine Pelham et al. with Lefere et al. as Lefere et al. discloses using a laxative to help clear the colon.

19. **Claims 36, 37, and 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,647,360 (herein referred to as Bani-Hashemi et al.). Bani-Hashemi et al. discloses a digital subtraction angiography method for 3D imaging of a volume of a body. A contrast agent is injected (col. 4 line 3) into the body in order to opacify the blood vessels. Opacifying the blood vessels reduces the attenuation signal of a patient's blood, after which a region of interest such as the heart can be imaged.

20. **Claims 38-40 and 42-44** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bani-Hashemi et al. as applied to claims 36 and 41 above and further in view of US Publication No. 2002/0061280 A1 (herein referred to as Mattrey). Mattrey discloses employing CT contrast agents, that are microns in size (paragraph 0034), that decrease electron density in certain areas (such as blood), that can be fat or air bubbles (paragraph 0039). It would be obvious to one with ordinary skill in the art at the time of the invention to combine Mattrey with Bani-Hashemi et al. as any contrast agent known in the art can be used for contrast enhanced imaging.

21. **Claim 45** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bani-Hashmi et al. in view of Lefere et al. Bani-Hashmi et al. discloses the method and the parts to injecting a contrast agent into a body for a CT angiography, but does not specifically disclose having a kit

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for it. Although Lefere et al. does not explicitly disclose a kit for CT angiography, it does disclose a kit for CT colonoscopy. Kits for procedures are well known in the art and it would be obvious to create a kit for other types of procedures, such as for CT angiography.


Conclusion

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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